K073696

APR - 8 2008

510(k) SUMMARY
J. Morita USA Inc.'s Veraviewepocs
X550

1. Submitter Name and Address with Phone/Fax :

Registration No. 2081055
Initial Distributor:
J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

Registration No. 3002807636
Manufacturer:
J. MORITA MFG. CORP.
680 Higashihama Minami-cho
Fushimi-ku, Kyoto
Japan 612-8533
+81-75-611-2141
+81-75-605-2353

2. Contact Person

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. Date summary prepared: December 14, 2007

4. Device Name:

Trade or Proprietary Name: Veraviewepocs Model : X550
(with 6 versions: X550-3DA/3DB/3DC, X550-2DA/2DB/2DC)

Common Name: Dental Panoramic/Cephalometric X-ray System with CT Capability

Classification Name: Extraoral Source dental X-ray System (21CFR872.1800)

Product Code : MUH

5. Substantial Equivalency is claimed against the following devices:

Veraviewepocs VE (K030699)
3D Accu-I-tomo XYZ Slice View Tomograph (K052587)
ProMax3D (K060328)

Description of the device:

raviewepocs (Model X550) is extraoral source Dental Panoramic X-ray unit with a frequency switching mode x-ray generator. In addition to panoramic exposure, the can also take scano-grams. Also cephalometric device is available that uses the oramic x-ray source.

rther more a three dimensional Cone Beam Computed Tomography (CBCT) is also ilable, which uses cone shaped x-ray beam projected onto a flat panel detector.

he main body of X550 includes a base, support column, lift, patient frame, movement and arm, and control box. The main body weighs approximately 184 kilograms and dimensions of 235.5cm (height), 102 cm (width), and 133 cm (depth).
he movement arm, with a X-ray sensor unit on one side of the patient's head and an head on the other hand, is rotated 180 degrees as an arm combined on movement . The movement unit with a patient frame, mounted to the lift, moves up and down ically along support column.

peration of the main body is performed by Control Panel and Control Box. Control el 1) selects exposure program, 2) raises up or lower down the lift, 3) positioning ns ON and OFF, 4) has ready key.
ontrol Box equips hand switch, emission button, emission light, ready light, main er switch, power light, and key switch.

Intended Use

e X550 is used with the purpose to obtain dental x-ray panoramic tomography ures, optionally with Cephalometric radiography and with three dimensional cone n computed Tomography, all of which are intended for dental radiographic mination and diagnosis of diseases of the teeth, jaw and oral structures.

8. Safety and effectiveness of the device

There are already two kinds of FDA- cleared devices in J. MORITA MFG. CORP. as follows in the Table below.

No.	Device	510(k) number	Functions of the device	NOTE
①	Veraviewepochs VE	K#030699	Dental digital x-ray panoramic with cephalometric radiography	2D
②	3D accu-i- tomo	K#052587	Dental x-ray computed tomography	3D

The Veraviewepocs (Model X550) is essentially a slightly modified device of ① by being added only with the computed tomography function of ②. The device accomplishes this task by reconstructing a three dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two (2D) images or three dimensional (3D) images.

So that, the X550 is not only an conventional extraoral source X-ray 2D imaging unit of digital panoramic/cephalometric used for dental radiographic examination and diagnosis of teeth, jaw, and oral structure , but also has and 3D imaging capability for Dento-maxillofacial.

The device is operated and used by physicians, dentists and x-ray technologists.

As described below, the X550 has the same general intended use, similar principles of operation, and similar technological characteristics as those of both previously cleared predicate devices, Veraviewepocs VE (K#030699) and 3D Accu-I-tomo (K#052587).

In addition, this sort of modification of adding 3D imaging capability over 2D imaging is completely identical to the case of the modification of Planmeca Oy's ProMax 3D (K#060328) under the reference of our 3D Accu-I-tomo (K#052587).

Consequently, it is self-explanatorily evident that this X550 is substantially equivalent to Planmeca Oy's ProMax 3D (K#060328) in the sense of the same general intended use, similar principles of operation, and similar technological characteristics.

Table-1 Comparison summary chart

	This new submission	Predicate	Difference
Name of the model	X550	ProMax 3D	Different
Manufacturer	J.MORITA MFD. CORP.	Planmeca Oy	Different
Construction	Rotating arm and base	Rotating arm and base	Similar
Image Receptor	Flat panel detector	Flat panel detector	Identical
Performance spec.	International standards	International standards	Similar
Mechanical	Morita made mechanism	Unknown mechanism	Presumably Similar
Electrical	Morita made electric circuit	Unknown electric circuit	Presumably Similar
Software	Morita made software	Unknown software	Different
Testing	Mainly done by VDE	Unknown	Presumably Similar

Table-2 Comparison summary table

FDA file reference number 510k number ; K060328

Model name of Predicate Device	**ProMax 3D**
510(k) number of Predicate Device	K060328
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indication for use	Identical
Target population	Identical
Design	Presumably similar
Materials	Similar
Performance	Similar
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Identical
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Identical
Electrical safety	Similar
Thermal safety	Identical
Radiation safety	Identical

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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J. Morita USA, Inc.
c/o Keith A. Barritt
Fish & Richardson P.C.
1425 K St. N.W.
Suite 1100
WASHINGTON DC 20005

Re: K073696
Trade/Device Name: Veraviewepocs 2D/3D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: March 4, 2008
Received: March 5, 2008

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(K) Number : ~~unknown~~ K073696

Device Name: Veraviewepocs 2D/3D

Indications for Use:

The Veraviewepocs is an extraoral source x-ray unit that is used for dental radiographic examination and diagnosis of teeth, jaw, oral structure, TM-joints and skull including the ENT and dento-maxillofacial areas, by exposing an X-ray image receptor to ionizing radiation. The device uses cone shaped x-ray beam projected on to a flat panel detector, and the examined volume image is reconstructed to be viewed in 2D or 3D viewing stations.

The device is to be operated and used by dentists and other legally qualified professionals.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use

(Part21CFR801 Subpart D) (Part21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use ✓ or Over-The-Counter Use

(Part21CFR801.109) (Optional Format 1-2-96)

Nancy C. Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number K073696